

the conditions of use prescribed in the label thereof, or under such conditions of use as are customary or usual.

"In determining whether or not the label in question in this case was false and misleading, you must approach the question from the viewpoint of a man of ordinary intelligence who might be suffering from constipation and desirous of being relieved of it. That is, the language used on the label should be given the meaning ordinarily conveyed by it, to whom it is addressed, and if you find beyond a reasonable doubt that the language so construed is false and misleading, then you would have to find the defendant guilty.

"The act seeks to protect those who might be induced to purchase the article by the representation made in the label, and the proper test for the construction of such language is what it means to such persons, and not necessarily to those who are skilled in medicine and medical or pharmaceutical science, capable of making necessary distinctions. Its purposes are to secure purity in foods and drugs; to inform purchasers of what they are buying; to prevent injury to the public health, and to require the manufacturer to be honest in his statements, those resulting from insufficient directions and ambiguity, as well as statements that are false, come within the contemplation of the act.

"Now gentlemen of the jury, if from the evidence in this case and under the instructions that the court has given you, you find this defendant guilty beyond a reasonable doubt of the offense charged in the indictment, then the form of your verdict would be, 'We, the jury, find the defendant guilty.' On the other hand, if you find him not guilty, then the form of your verdict would be, 'We, the jury, find the defendant not guilty.' You may retire."

The jury, after due deliberation, returned a verdict of guilty and the court placed the defendant on probation for 1 year.

SEIZURES

376. Misbranding of Electreat Mechanical Heart. U. S. v. 6 Electreat Mechanical Hearts. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 1736. Sample No. 16222-E.)

The labeling accompanying this device bore false and misleading representations regarding its efficacy in the conditions indicated below.

On April 2, 1940, the United States attorney for the Western District of Missouri filed a libel against six of the above-named devices at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about March 6, 1940, by the Electreat Manufacturing Co. from Peoria, Ill.; and charging that it was misbranded.

Examination showed that the device consisted of dry cells, a small buzzer coil, and various attachments intended to apply electrical currents to the body.

The article was alleged to be misbranded in that statements appearing on the carton and in an accompanying circular and booklet were false and misleading since they represented that it was efficacious for the purposes recommended; whereas it was not efficacious for such purposes. The respect in which the labeling was false and misleading appears in the opinion of the court.

On May 5, 1940, the Electreat Manufacturing Co. appeared as claimant and on July 18, 1940, filed an answer denying the allegations of misbranding. On February 28, 1941, the case having come on for trial before the court and the evidence having been heard and considered, the court handed down the following opinion sustaining the Government's allegations:

COLLETT, *District Judge*. "On March 6, 1940, six devices called Electreat Mechanical Hearts were mailed in interstate commerce¹ from Peoria, Ill., to Kansas City, Mo., for the purpose of sale at the latter place. The devices were seized by the Government and libel proceedings instituted at Kansas City, Mo., for the purpose of bringing about the destruction of the devices.

"The Federal Food, Drug, and Cosmetic Act of June 25, 1938 (Title 21, Sec. 301 et seq. U. S. C. A.) authorizes the destruction of misbranded devices.² The

¹ "Sec. 321 (b): The term 'interstate commerce' means (1) commerce between any State or Territory and any place outside thereof * * *."

² "Sec. 334 (a): Any * * * device * * * that is * * * misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *."

term 'device' is defined in the act.³ The statute provides that if the device is alleged to be misbranded because of misleading labeling, in the determination of that question there shall be taken into account, among other things, not only representations made in the labeling but also the extent to which the labeling fails to reveal material facts.⁴ 'Labeling' is defined to include all labels and other written, printed, or graphic matter upon the article or any of its containers or wrappers or accompanying the article.⁵ The libel charges false and misleading labeling. The good faith of the manufacturer is not an issue. The inherent dangerousness of the device or lack of it is of no consequence. The issue is simply whether the claims made for the device are false or misleading.

"The principal and most numerous claims made for the device are contained in a booklet which accompanied the devices seized. There the device is referred to as 'The Mechanical Heart.' In the language of the booklet it will relieve pain, strengthen weak eyes, soothe sore eyes, improve the hearing, cure earache, moisten dry noses or dry running noses, thicken thin lips, relieve toothache, strengthen the voice, relieve sore throat, build up weak lungs, relieve pleurisy, strengthen the kidneys, cure lumbago, relieve constipation, soothe the piles, is good for neuritis, subtracts pain from burns, relaxes the muscles in a stiff thumb and soothes the pain in a mashed finger, retards or accelerates the development of a boil, heals broken noses, relaxes muscle cramps, is good for varicose veins and will warm cold feet or stop the foot from perspiring.

"The booklet undertakes to demonstrate 'why the good die young,' what the 'father and mother' of disease is, the cause of wakefulness, how to grow strong, and the corrective qualities of the device in each instance.

"It then gives specific directions about how to use the Electreat for the treatment of headache, neuralgia, sinus congestion, neuritis, sore throat, weak lungs, athletic strains, lumbago, rheumatism, gout and tired feet, stomach, indigestion and cramps, kidney and bladder trouble, liver disorders, constipation, piles, sexual weakness male and female, menstruation, menopause, enlarged prostate, paralysis, deafness and catarrh, toothache, eye ailments, asthma, hay fever, flu, broken bones, burns, cuts, sores, hardening of arteries, cramps of the calf, nervousness, to reduce weight or increase weight as desired, beautification of the skin, enlarge the bust and increase the flow of milk, and to stop falling hair. Then follows a number of testimonials affirming the efficacy of Electreat for the treatment of many and sundry bodily ailments ranging from congenital and jake-leg paralysis through heart ailments, piles, rejuvenation, to appendicitis and female trouble. The testimony of the manufacturer who intervened in the cause as claimant, indicates that the theory upon which the multitudinous claims were made was that the instrument produces a faradic electrical current with the alternating impulses occurring at the rate of from 140 to 180 times a second, which would cause the muscles and muscular tissue of the human body to contract and relax with beneficial results. The instrument is simple enough. It consists of a cylindrical metal container having much the appearance of an ordinary flashlight, approximately 10 to 11 inches long, an inch and a half in diameter with two small flashlight batteries in one end and in the other two coils. The primary coil is wound upon a soft iron core. The secondary coil is so wound that it may be moved longitudinally over the primary coil by means of a button attached to it and extending through the metal cylinder much as the switch on an ordinary flashlight is arranged. A common vibrator such as might be used on the old-fashioned doorbell, makes and breaks the current from the battery and transforms the galvanic current from the battery into the faradic or alternating current, which is delivered to the body through a projection on one end of the instrument. The strength of the charge delivered to the body from the instrument is increased or decreased by means of sliding the secondary coil further over or away from the primary coil.

³ "Sec. 321 (h) : The term 'device' * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

⁴ "Sec. 321 (n) : If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

⁵ "Sec. 321 (m) : The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

"An adequate amount of highly respectable and convincing testimony was offered by the Government to demonstrate that even the principle sought to be followed by the makers of the instrument could not be applied with this instrument. It was explained that the speed or rapidity at which muscular tissue could contract and relax was much less than the rate at which the vibrations occurred in this instrument and the alternating impulses were given, and hence the only effect from the use of the instrument on the muscles of the body was to cause them to contract and remain so until the instrument was removed, the batteries wore out, or the muscles relaxed from fatigue. Many of the particular claims made for the instrument were specifically referred to by the witnesses. In each instance the explanation of why the instrument could not produce the results claimed for it was most convincing.

"Among others appearing for the Government was the eminent physiologist, Dr. Carlson. His testimony and the illustrations he gave supporting his conclusions were in all respects as fully convincing of the accuracy of his judgment as was his test for the determination of which of two fluids was a sugar solution.*

"The extent of the accuracy of the actual claims made for the Electreat in the literature accompanying it may be summarized much as one of the witnesses expressed it when, in describing a diagram of the human anatomy with accompanying descriptive matter which appeared in one of the exhibits, he stated that there was an element of truth in the diagram, the element of truth being—that the head was on the right end in the picture and the 'rump' appeared in the proper position. From a practical standpoint, the benefit to be derived from the use of the instrument was tersely stated by one of the several leading physicians of Kansas City, to be that the use of the instrument would not injure one if there was nothing the matter with him, but that if a person was suffering from any disorder or ailment its use might and probably would be injurious.

"Further detailed reference to the facts should be unnecessary to demonstrate the irresistible conclusion arising from the evidence that the claims made for the devices in the literature accompanying them were as falsely misleading as might well be possible by the use of the English language. The conclusion follows that the act of Congress has been violated and the requested order for the destruction of the devices must be made.

"It is beyond the issues in this proceeding to consider the question of whether, if the devices were properly described and labeled and their efficacy stated without exaggeration, the devices could be barred from the mails and interstate commerce. Hence, evidence bearing upon that question admitted subject to objection, is excluded from consideration.

"Neither is the question of whether the manufacturer acted in good faith in an honest belief that the devices would do the things claimed for them an issue in this proceeding. The Government does not seek a penalty in this case other than the destruction of the devices. Evidence bearing upon that question, likewise admitted subject to objection, should also be excluded.

"Formal findings of fact and conclusions of law are filed herewith. Judgment will be entered in accordance with the views herein expressed."

On February 28, 1941, judgment was entered (amended March 10, 1941) ordering that the marshal destroy the product. On March 20, 1941, the claimant filed a motion for a rehearing and application for stay of proceedings which were argued April 25, 1941, and denied by the court without opinion.

377. Misbranding of El Aguinaldo Cuban Honey. U. S. v. 50 Bottles of El Aguinaldo Cuban Honey (and 3 other seizure actions involving the same product). Default decrees of condemnation. Portion of product ordered destroyed; remainder ordered delivered to charitable institutions. (F. D. C. Nos. 2498, 2725, 3438, 3462. Sample Nos. 8932-E, 8937-E, 27491-E, 27495-E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On August 6, September 4, November 27, and December 5, 1940, the United States attorneys for the District of Minnesota and the Southern District of Ohio filed libels against 50 bottles of El Aguinaldo Cuban Honey at St. Paul, Minn.; 118 bottles of the same product at Minneapolis, Minn.; and 171 bottles at Cincinnati, Ohio, alleging that the article had been shipped in interstate commerce within the period from on or about December 27, 1939, to on or about

* "Time magazine, February 10, 1941, page 44, l. c. 47: Another time he had two beakers of liquid before him: one containing urine, the other, sugar solution. He stuck his finger in one of the containers, tested it and said: 'Ya, dot's sugar.'"